

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

JAPANESE FOUNDATION FOR
CANCER RESEARCH

Plaintiff,
v.

TERESA STANEK REA, Acting Under
Secretary of Commerce for Intellectual
Property and Acting Director of the United
States Patent and Trademark Office,

UNITED STATES PATENT AND
TRADEMARK OFFICE,

Defendants.

Civil Action No. 1:13-cv-412
(AJT/TRJ)

MEMORANDUM OPINION

On October 11, 2011, a terminal disclaimer of U.S. Patent No. 6,194,187 was filed with the United States Patent and Trademark Office (“PTO”) on behalf of the patent owner, plaintiff Japanese Foundation for Cancer Research (the “Foundation”).¹ After the disclaimer was filed, but before it was published on the PTO’s website or in the PTO’s *Official Gazette*, the

¹ Generally, the term of a patent is twenty years from the filing date of the patent application. 35 U.S.C. § 154(a)(2). A “terminal disclaimer” refers to a patentee’s formally disclaimer, and dedication to the public, of part of a patent term. Such disclaimers are generally used by patent applicants to avoid what is referred to as an “obviousness-type double patenting” rejection by the PTO based on “an ‘obvious’ modification of the same invention [already patented].” *In re Longi*, 759 F.2d 887, 892-93 (Fed. Cir. 1985). A rejection on this basis is intended to protect the public from an “unjustified timewise extension” of a patent. *Boehringer Ingelheim Intern. GmbH v. Barr Lab., Inc.*, 592 F.3d 1340, 1347-48. (Fed. Cir. 2010). To avoid such a rejection of a new patent application, a terminal disclaimer will be filed as part of the new patent application, with the result that the new patent will issue with a term that expires at the same time as the earlier, already issued patent. *Id.*

Foundation requested that the PTO withdraw the disclaimer on the grounds that the Foundation had never authorized its filing. The PTO denied the Foundation's repeated requests to withdraw the terminal disclaimer, published it on its website (with a statement that it was being contested), and ultimately issued its Final Agency Decision ("FAD") on February 22, 2013, denying the Foundation's request. The PTO summarized its decision as follows:

There is no dispute that pursuant to 35 U.S.C. [§] 253 and in compliance with 37 C.F.R. [§] 1.321(a), the disclaimer was filed in writing (with the required fee) by the assignee of the entire interest [the Foundation]. The [Foundation] disclaimed 'the entire term of all claims in Patent No. 6, 194, 187.' By this statement, [the Foundation] relinquished legal rights to all claims of this patent. By law, such disclaimer shall be recorded by the Office and is considered part of the original patent. Such disclaimer is binding upon the grantee and its successors or assigns.

Patentee [the Foundation] seeks for the Office to invoke the discretion of the Director and to suspend the rules and withdraw the disclaimer. However, under the circumstances of the filing of this statutory disclaimer in a patented case, the office is without authority to return to patentee the freely disclaimed term of all claims in Patent No. 6, 194, 187.

Doc. No. 25-8, FAD at 4.

On April 1, 2013, the Foundation filed this action seeking to reverse the FAD under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 on the grounds that the PTO's refusal to allow withdrawal of the terminal disclaimer, under the particular circumstances of this case was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See* 5 U.S.C. 706(2)(A). Presently pending before the Court are the parties' cross motions for summary judgment [Docs. No. 13, 22]. A hearing was held on those motions on May 10, 2013, following which the Court took the motions under advisement.

The PTO does not contest or challenge in its FAD that the disclaimer was filed without the Foundation's authorization.² The Court therefore concludes that the PTO: (1) erred as a matter

² While the PTO in its FAD does not dispute that the Foundation did not authorize the filing of the disclaimer, it did not make any specific findings in that regard. Upon remand, the PTO will

of law when it ruled that the Foundation was bound by an unauthorized filing of the terminal disclaimer and refused for that reason to withdraw the unauthorized disclaimer; (2) erred as a matter of law when it ruled that it was without inherent authority to withdraw the disclaimer under the circumstance of this case; and (3) abused its discretion when it ruled that it would not exercise any inherent authority it did have to withdraw the disclaimer. The Court will therefore GRANT the Foundation's motion, DENY the PTO's motion, and direct the PTO to withdraw the terminal disclaimer, absent a finding that the Foundation actually authorized its filing.

I. BACKGROUND

The Foundation is a non-profit entity, organized under the laws of Japan with its principal place of business in Tokyo, Japan. It was established in 1908 and was the first institute in Japan specializing in cancer research. Its work is funded, in part, through royalties collected from licensing its intellectual property.

On February 27, 2001, a patent entitled "Apoptosis-inducing protein and gene encoding the same," U.S. Patent No. 6,194,187 (the "Cancer Treatment Patent"), was issued to its inventor and assigned to the Foundation. Doc. No. 25-3, 25-7. The Cancer Treatment Patent was scheduled to expire on April 17, 2017. Doc. No. 25-3. Following its issuance, the Foundation licensed rights to practice it to two pharmaceutical companies, Kyowa Hakko Kirin, Inc. ("KHK") and Carna Biosciences ("Carna") (collectively the "licensees"). The Foundation did not grant the licensees the right to disclaim the Cancer Treatment Patent, or any part of its term.

In 2011, KHK, one of the Foundation's licensees, acting through its in-house counsel, called KHK's outside Japanese counsel, Kyowa Patent and Law Office ("Japanese Licensee

have the opportunity to make whatever inquiry it deems necessary to determine the authorization *vel non* of the disclaimer's filing.

Counsel),³ and inquired generally about the process of filing a terminal disclaimer under United States patent laws. Doc. 25-8, Saito Decl. ¶ 5. Based on that conversation, Japanese Licensee counsel believed that KHK's in-house counsel had orally requested that a terminal disclaimer of the Cancer Treatment Patent be filed on behalf of the Foundation. Doc. 25-8, Kinoshita Decl. ¶¶ 3, 6. Japanese Licensee Counsel did not seek any formal, written request or confirmation from KHK and did not attempt to contact the Foundation. *Id.* ¶ 7. Instead, on March 9, 2011, Japanese Licensee Counsel sent a fax to the American law firm Foley & Lardner LLP ("U.S. Counsel), which served as the Foundation's attorney of record with the PTO, instructing it to "abandon the captioned patent positively and invalidate this patent before the case lapses by non-payment of the next maintenance fees, which will be due on August 27, 2012." Doc. No. 25-8 at 16.

On October 11, 2011, U.S. Counsel filed the terminal disclaimer with the PTO and forwarded a copy to Japanese Licensee Counsel. Doc. No. 25-7 at 170-71. Japanese Licensee Counsel forwarded a copy to KHK. On November 30, 2011, after receiving the copy of the terminal disclaimer, KHK's in-house patent counsel contacted Japanese Licensee Counsel and informed them that KHK had not requested the disclaimer. Doc. No. 25-8, Okubo Decl. ¶¶ 5-7. For these reasons, KHK instructed Japanese Licensee Counsel to take the necessary steps to withdraw the terminal disclaimer. *Id.* ¶ 10. On November 30, 2011, Japanese Licensee Counsel sent to U.S. Counsel a fax marked "EXTREMELY URGENT" requesting that U.S. Counsel take the proper steps to withdraw the disclaimer. U.S. Counsel proposed filing a petition to withdraw with the PTO and, on December 1, 2011, Japanese Licensee Counsel directed U.S. Counsel to

³ Despite sharing the same first word—Kyowa—KHK and Japanese Licensee Counsel are not under common ownership or otherwise affiliated with one another.

prepare the petition. *Id.* ¶ 10. On December 9, 2011, U.S. Counsel sent Japanese Licensee Counsel a draft petition, which was approved on December 13, 2011. That same day, U.S. Counsel filed its first “Petition under 37 C.F.R. § 1.182 to Withdraw the Statutory Disclaimer.” Doc. No. 257 at 176-78.⁴

After this first petition was filed, but before the PTO took any action on it, the PTO posted the terminal disclaimer on its internet website portal known as “PAIR”, an acronym for Patent Application Information Retrieval, thereby making it electronically accessible to the public for the first time. Then, on January 17, 2012, the PTO dismissed the December 13, 2011, petition, essentially on the grounds that the PTO did not have statutory authority to withdraw the terminal disclaimer.⁵ In response, U.S. Counsel filed a series of petitions on behalf of the Foundation, citing authority it believed demonstrated that the PTO had discretion to withdraw the disclaimer. The first of these subsequent petitions, filed on February 27, 2012, and styled

⁴ 37 C.F.R. § 1.182 provides:

All situations not specifically provided for in the regulations of this part will be decided in accordance with the merits of each situation by or under the authority of the Director, subject to such other requirements as may be imposed, and such decision will be communicated to the interested parties in writing. Any petition seeking a decision under this section must be accompanied by the petition fee set forth in § 1.17(f).

⁵ In denying the Foundation’s request, the PTO advised the Foundation as follows:

[T]he policy of the Office is well established. The USPTO will not grant a request to withdraw or amend a recorded terminal disclaimer in an issued patent on the grounds that the rules of practice and 35 U.S.C. [§] 253 do not include a mechanism for withdrawal or amendment of such a terminal disclaimer.

Doc. No. 25-7 at 204-05.

“Petitions under 37 C.F.R. § 1.182 and § 1.183,” sought to withhold the terminal disclaimer from publication in the *Official Gazette*.⁶ Doc. No. 25-7 at 206-08.

The PTO did not respond to this petition, and on March 16, 2012, the Foundation filed an additional petition, together with sworn declarations, styled “Request for Reconsideration of Decision on Petition or, in the Alternative, Petition under 37 C.F.R. §§ 1.182 and 1.183 to Invoke the Discretion of the Director and Suspend the Rules.” Doc. No. 25-7 at 209; *see also* Doc. No. 25-8 at 12-21. For several months, the PTO took no action with respect to these petitions. On August 7, 2012, U.S. Counsel met with the Director of the Office of Petitions and the attorney in that office assigned to the case. Doc. No. 25-8 at 24. Following that meeting, on August 30, 2012, U.S. Counsel filed a “Supplemental Petition for Reconsideration,” requesting that the PTO exercise its inherent authority to set aside the “invalid” terminal disclaimer. *Id.* at 25-26.

Nearly six months later, on February 22, 2013, the PTO issued its FAD, in which it denied all of the Foundation’s requests for relief and ordered publication of the terminal disclaimer in the *Official Gazette*. Doc. No. 25-8 at 40-50. On March 14, 2013, the Foundation filed a petition styled “Request to Withhold Recordation and Publication of the Notice of Unauthorized Disclaimer in the Official Gazette, Pending Judicial Review of the Agency’s Decision, or in the Alternative, Petitions Under 37 C.F.R. §§ 1.182 and 1.183 to Invoke the Discretion of the Director and Suspend the Rules.” On March 21, 2013, the PTO denied the Foundation’s request not to publish the disclaimer in the Official Gazette, but later agreed to

⁶ 37 C.F.R. § 1.183 provides:

In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director’s designee....

preserve the status quo pending judicial review.⁷ On April 1, 2013, the Foundation appealed the FAD pursuant to the APA.

II. Standard of Review

A. Summary Judgment Standard

Summary judgment should be granted where the record shows that “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Entry of summary judgment is appropriate “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The non-moving party must go beyond the pleadings and mere allegations and “set forth specific facts showing that there is a genuine issue for trial.” *Id.* at 323. “[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment.” *Anderson*, 477 U.S. at 247-248 (emphasis in original). Indeed, “[i]f the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted).

In an action brought under the APA there is no material fact at issue but only a question of law:

When a party seeks review of agency action under the APA before a district court, the district judge sits as an appellate tribunal. The entire case on review is a

⁷ After the PTO denied its request not to publish the disclaimer in the *Official Gazette*, the Foundation filed this action on April 1, 2013, and then on April 5, 2013, filed a Motion for Preliminary Injunction to Preserve the Status Quo Pending Judicial Review [Doc. No. 3]. Before the hearing scheduled on this motion, the parties reached an agreement on April 11, 2013 whereby the PTO agreed not to publish the terminal disclaimer as to the Cancer Treatment Patent in the *Official Gazette* unless and until the entry of final judgment in the PTO’s favor in this action. *See* Doc. No. 8.

question of law, and the complaint, properly read, actually presents no factual allegations, but rather only arguments about the legal conclusions to be drawn about the agency action.

Klock v. Kappos, 731 F. Supp. 2d 461, 465 (E.D. Va. 2010); *see also Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009); *Marshall Cnty. Health Care Auth. V. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993) (“[W]hen an agency action is challenged. . . the entire case on review is a question of law.”).

B. Judicial Review under the Administrative Procedures Act

Under the APA, an agency action may be set aside if the court finds that action was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. 706(2)(A). “The foregoing statutory criteria render our oversight ‘highly deferential, with a presumption in favor of finding the agency action valid,’ yet the arbitrary-and-capricious standard does not ‘reduce judicial review to a rubber stamp of agency action.’” *Friends of Back Bay v. Army Corps of Eng’rs*, 681 F.3d 581, 587 (4th Cir. 2012) (quoting *Ohio Valley Envtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009)). “[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). “Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to difference in view or the product of agency expertise.” *Id.* The burden of showing the agency action was arbitrary and capricious lies with the plaintiff. *See Ohio Valley Envtl. Coal.*, 556 F.3d at 192. Questions of statutory interpretation, however, are reviewed *de novo*. *See., e.g., Superior*

Fireplace Co. v. Majestic Products, Co., 270 F.3d 1358, 1369 (Fed. Cir. 2001); *Welch v. Chao*, 536 F.3d 269, 276 (4th Cir. 2008)(“Under the Administrative Procedure Act. . . [the Court] review[s] questions of law *de novo*.”)

III. Analysis

In the FAD, the PTO based its decision essentially on three grounds: (1) the Foundation was bound by its counsel’s filing of the disclaimer; (2) the PTO lacked both statutory and inherent authority to withdraw the terminal disclaimer; and (3) even if the PTO had inherent authority, it would not exercise its discretionary inherent authority to permit withdrawal of a duly filed disclaimer. The Court reviews the PTO’s first position as a matter of law. It also reviews as a matter of law whether the PTO has inherent authority to permit withdrawal of a disclaimer, but reviews under the APA’s arbitrary and capricious/abuse of discretion standard its decision not to exercise any inherent authority it has. The Court will uphold the PTO’s findings of fact, if supported by substantial evidence. *See Knox v. U.S. Dep’t of Labor*, 434 F.3d 721, 723-24 (4th Cir. 2006).

A. The PTO erred as a matter of law when it ruled that the Foundation was bound by the unauthorized filing of the terminal disclaimer.

At its core, the FAD rests upon the proposition that the Foundation is bound by its U.S. Counsel’s filing of the disclaimer, regardless of whether or not it was authorized, intentional, or necessary, citing as authority *Link v. Wabash R. Co.*, 370 U.S. 626 (1962). *See* FAD at 8 (“The inquiry ended at the office when the disclaimer was filed by an attorney of record for an assignee of record.”). In *Link*, the United States Supreme Court held that, notwithstanding the impact on the client, it was within the district court’s discretion to dismiss a case for failure to prosecute where a lawyer, with notice of his obligation to attend a pre-trial conference, failed to attend in a case where it could be reasonably inferred that “the [plaintiff] has been deliberately proceeding

in a dilatory fashion.” *Id.* at 633. Under the circumstances of that case, the Court found no merit to the claim that dismissal of the client’s case because of his counsel’s unexcused conduct “imposes an unjust penalty.” *Id.* Here, the situation is quite different. The patent disclaimer was not related to the prosecution of any patent applications or other legal proceedings committed by the Foundation to its counsel. There was nothing that required the disclaimer to be filed; and it was not filed for the usual purpose of avoiding or curing an “obvious-type” rejection of an applied for patent. Rather, without any obligation to do so, and without the Foundation’s authorization, the Foundation’s counsel filed a disclaimer that had the effect of nullifying the Foundation’s already issued and presumed valid patent.

It is generally recognized that, while clients are bound by the procedural, tactical or case management decisions of their counsel, clients are not bound by the unauthorized acts of their counsel concerning decisions pertaining to their fundamental rights over which they retain final and sole authority. These issues include such matters as whether to file suit, dismiss an action, release claims and settle a dispute. The scope of their authority to act solely by virtue of their representation simply does not extend to such matters. *See Auvil v. Grafton Homes, Inc.*, 92 F.3d 226, 230 (4th Cir. 1996) (holding there is no implied authority on the part of an attorney to settle a case, even where an attorney is authorized to conduct settlement negotiations and on that basis vacating settlement agreement where attorney settled a lawsuit without the actual authority of the client); *see also Sioux Tribe of Indians v. United States*, 862 F.2d 275, 279-80 (Fed. Cir. 1988) (recognizing the rule that a client is not bound by an unauthorized settlement but holding that a “stipulation of facts,” on the basis of which the Court entered its judgment was “not a settlement agreement which required the consent of the [client][,]” but rather “exactly the type of determination (*i.e.*, analysis of the evidence) that attorney can undertake ‘as part of the normal

conduct of litigation without the necessity for obtaining the approval of their client.”); *Snyder-Falkinham v. Stockburger*, 249 Va. 376, 381 (1995) (“An attorney at law, merely by virtue of being retained by the client, has no authority to compromise the client’s claim without the latter’s consent.”). *See generally*, Restatement (Third) of Law Governing Lawyers, § 22 (Rule applies to settlements and “comparable decisions”).⁸

The terminal disclaimer filed with respect to the Foundation’s Cancer Treatment Patent essentially waived and released the Foundation’s legal rights and entitlements with respect to a valuable asset. It effectively eliminated and destroyed the Foundation’s property rights. *See Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (“[A] patent is a form of property right, and the right to exclude recognized in a patent is but the essence of the concept of property.”) (citing *Schneek v. Norton Corp.*, 713 F.2d 782 (Fed. Cir. 1983)). In its effect, a disclaimer is comparable to a legal release, waiver or forfeiture. It also inflicted a harm, *viz.*, the loss of the patent’s exclusionary benefits, generally considered not adequately compensable with damages and irreparable absent its enforcement through equitable relief. *See, e.g., Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed.Cir. 2013). Here, its filing was not legally required or necessary to comply with any legal obligation of the Foundation or its counsel in any on-going litigation or proceedings. Nor was it filed, as it usually is, to avoid an obvious-type double patenting rejection and obtain the issuance of a patent. For these reasons, counsel’s conduct in this case is fundamentally different from an attorney’s failure to prosecute a

⁸ Section 22 provides in pertinent part:

(1) As between client and lawyer. . . the following and comparable decisions are reserved to the client except when the client validly authorized the lawyer to make the particular decision: whether and on what terms to settle...” Comment *e* to Section 22, *comparable decisions*, states that “the principles applicable to settlements also apply to significant contracts outside the litigation context, for example contracts to sell the client’s real estate. A client may authorize a lawyer to act in such matters, but otherwise the lawyer lacks authority.”

case in violation of court imposed duties and obligations, or even the authorized filing of a disclaimer that turns out to be mistaken in some aspect. It was beyond the scope of any authority U.S. Counsel had as a result of his representation of the Foundation before the PTO; and just as an attorney cannot settle a case or waive a client's property or contract rights without actual authority, the Foundation's counsel could not validly disclaim the Foundation's Cancer Treatment Patent without its actual authorization; the disclaimer's validity cannot issue from the implied, apparent authority of its counsel. For these reasons, the PTO acted contrary to law when in the face of sworn declarations establishing that the disclaimer was filed without the Foundation's actual authorization, concluded that the Foundation was nevertheless bound by its counsel's conduct and on that basis, ended its inquiry into the Foundation's request for withdrawal of the disclaimer once it determined that the disclaimer was filed by the Foundation's counsel of record. In fact, based on this administrative record, once the PTO satisfied itself that the disclaimer was in fact filed without the Foundation's authorization, its inquiry should have ended in favor of withdrawing the disclaimer.

The Court can discern no reason why this generally recognized rule protecting the Foundation's fundamental rights and expectations should not apply within the context of the PTO. In particular, the Court finds nothing in the PTO's rules of practice⁹ or its various

⁹ 37 C.F.R. § 1.34, pertaining to patent counsel, does not support any other result. Under that regulation:

When a patent practitioner acting in a representative capacity appears in person or signs a paper in practice before the United States Patent and Trademark Office in a patent case, his or her personal signature shall constitute a representation to the United States Patent and Trademark Office that . . . he or she is authorized to represent the particular party on whose behalf he or she acts. In filing such a paper, the patent practitioner must set forth his or her registration number, is or her name and signature. Further proof of authority to act in a representative capacity may be required.

concerns and considerations mentioned in the FAD that would justify nullifying the Foundation's patent under the circumstances of this case. For example, the PTO's general, unparticularized concerns and considerations pertaining to the public's right to rely on the public record are not supported by any specific findings of institutional harms or prejudice to the public.¹⁰ The FAD also ignores that the rights, if any, of someone who has relied on the disclaimer before its withdrawal can be appropriately considered and protected within the context of infringement litigation. *See Carnegie Mellon University v. Schwartz*, 105 F.2d 863, 867 (3d Cir. 1997) (where the Court observed that the legal effect of a disclaimer the PTO's had erroneously filed and then "deleted" over 15 months later and then again "corrected" nearly five years later could be decided in the patent infringement litigation pertaining to the disclaimed patent).¹¹ Moreover, concerns based on the need to preserve the integrity of the PTO's filing system would appear to push strongly in favor of a policy that unauthorized, patent eliminating disclaimers will be purged from the public record. As shown in *Carnegie Mellon*, the legal effect of an unauthorized disclaimer will likely be challenged in collateral proceedings; and absent such a PTO policy, the

Nothing in this regulation can be read to say that anything a counsel of record files will be conclusively deemed to have been filed with actual authority. In fact, the above rule states only that it will be presumed that counsel is authorized to "represent" a party. It says nothing about what conduct will be deemed to be within counsel's scope of authority based on that representation. If it says anything in that regard, the rule appears to contemplate that an attorney may only act with actual authority. ("Further proof of authority [of an attorney of record] to act in a representative capacity may be required.").

¹⁰ In terms of harm to the public, the PTO concedes that there is no evidence of any actual reliance on the disclaimer and the only publication of the disclaimer beyond the public filing itself was through PAIRS on its website, accompanied by a notice that the validity of the disclaimer was under review. The prospects that someone has actually reasonably relied on the disclaimer are therefore minimal.

¹¹ In *Carnegie Mellon*, the PTO took the position that its Erratum and Certificate of Correction operated retroactively to cure the erroneous disclaimer that it had filed, such that alleged infringers of the disclaimed patent had not acquired any intervening rights. *See id.* at 865-86.

possibility that unauthorized disclaimers may remain on the public record with the PTO's knowledge or approval would surely place a cloud over the PTO's public record and the extent to which the public can, in fact, safely rely on it.

Nor can the PTO's administrative necessity or convenience concerns justify depriving the Foundation of its patent based on the unauthorized disclaimer. In this regard, the PTO claims that withdrawing the disclaimer in this case would lead to an influx of similar requests that would overtax its resources. *See* Def. Br. at 18 (If the PTO permitted the withdrawal of a disclaimer, "[a] party could attempt to nullify a patent filing merely by alleging that the filing was unauthorized, and agency personnel would be required to expend their resources investigating the motives and intent of the patentee when it made the disputed filing."). But again, the PTO made no factual findings in this regard, based on past requests or any other measure, and there is nothing in the administrative record that would support these claims, particularly since terminal disclaimers are generally filed purposefully to avoid an "obviousness-type double patenting" rejection. *See In re Longi*, 759 F.2d at 892-93. *See Universal Camera Corp. v. N.L.R.B.*, 340 U.S. 474, 463 (1951) (courts do not have to defer to agency findings of facts that are not supported by substantial evidence). There is also nothing in the administrative record that supports the PTO's claim in this Court that it does not have the institutional competence to consider the Foundation's request on the merits, which raises issues no different in substance or complexity than other issues that may confront the PTO under statutes and regulations it is charged with administering. *See, e.g.*, 35 U.S.C. § 253 (requiring that the filing party have no "deceptive intention"); 37 C.F.R. § 1.183 (authorizing the Director to act "as justice requires").

Lastly, the PTO's reliance on public policy cannot overcome the Foundation's rights to its patent absent an authorized disclaimer. Here, the Foundation is not seeking to recapture something that it "freely dedicated to the public." The disclaimer was filed without the Foundation's authorization and there is no evidence of any bad faith or fraud on its part in connection with the filing. Once it learned of the unauthorized filing, the Foundation acted expeditiously under the circumstances to undo it and in fact placed the PTO on notice of the unauthorized filing before the PTO took any action to publish the disclaimer through its website. In summary, nothing the PTO relied upon in the FAD would trump or outweigh the harm inflicted on the Foundation by the unauthorized filing.

B. The PTO has the authority to withdraw the disclaimer.

The PTO denied the Foundation's request to withdraw the disclaimer on the grounds that it did not have either statutory or inherent authority to do so and even if it did have such authority, withdrawal was not warranted under the circumstances of this case. The Court concludes that the PTO had inherent, discretionary authority to withdraw the unauthorized disclaimer and it abused its discretion when it refused to do so.¹²

¹² The Court agrees with the PTO that neither Section 253 nor 255, separately or when read together, explicitly authorize the PTO to withdraw the unauthorized disclaimer. Section 253 provides no basis for relief since that section simply authorizes the filing of a partial or total disclaimer, with no mention of any right to withdraw a disclaimer or any procedure for requesting its withdrawal. *See Bayer AG v. Carlsbad Tech.*, 298 F.3d 1377 (Fed. Cir. 2002) ("Section 253, which permits filing of a terminal disclaimer and 'dedication to the public' of the terminal part of the term, does not include a mechanism for withdrawal or amendment of a terminal disclaimer."); *see also Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317 (Fed. Cir. 2007) ("[W]e held in *Bayer* that a terminal disclaimer could not be withdrawn."). Section 255 does authorize a corrective filing, but only for "mistake[s] of a clerical or typographical nature, or of minor character." 35 U.S.C. § 253. An unauthorized filing of a terminal disclaimer cannot be reasonably characterized as a "clerical" mistake since it was in proper form and filed with respect to the intended patent. For the same reasons, its filing was not a "typographical" mistake. Nor was it of "minor character" given its legal effect on the enforceability of the patent. The Foundation argues that Section 255 is analogous to Fed. R. Civ.

The PTO takes the position that because it has no explicit statutory authority to withdraw the disclaimer, it has no inherent authority to withdraw a terminal disclaimer, citing *Bayer AG* and *Merck & Co., Inc.* for the proposition that a terminal disclaimer may *never* be withdrawn. *See id.* at 10 (“[T]he [PTO] will not grant a request to withdraw or amend a recorded terminal disclaimer in an issued patent on the grounds that the rules of practice and 35 U.S.C. [§] 253 do not include a mechanism for withdrawal nor amendment of such a terminal disclaimer. . . .”). The Court concludes, as a matter of law, that the PTO has the inherent, discretionary authority to withdraw an unauthorized terminal disclaimer, even though not specifically authorized by statute.

“Whenever a question concerning administrative, or judicial, reconsideration arises, two opposing policies immediately demand recognition: the desirability of finality, on the one hand, and the public interest in reaching what ultimately appears to be the right result on the other.” *Civil Aeronautics Bd. v. Delta Airlines, Inc.*, 367 U.S. 316, 321 (1961). The exercise of inherent authority “is often the sole means of correcting errors of procedure or substance.” *Bookman*, 453 F.2d at 1265. *See also Macktal v. Chao*, 286 F.3d 822, 825 -26 (5th Cir. 2002) (“[I]t is generally accepted that in the absence of a specific statutory limitation, an administrative agency has the inherent authority to reconsider its decisions.”) (cited with approval in *Tokyo Kikai Seisakusho, Ltd. v. U.S.*, 529 F.3d 1352 at 1360 (Fed Cir. 2008)).

P 60(b), which permits relief from a final judgment, order, or proceeding to correct errors resulting from “mistake, inadvertence, surprise, or excusable neglect” or “any other reason that justifies relief.” Fed. R. Civ. P. 60(b). The substantial differences between Rule 60(b) and Section 255 are clear on the face of these provisions. The Court does agree, however, with the Foundation’s position that nothing in these statutes prohibits the withdrawal of unauthorized disclaimers.

Section 253 authorizes a patentee or patent applicant to disclaim “the entire term, or any terminal part therein of the patent granted or to be granted.”¹³ The PTO’s regulations prescribe the procedure for utilizing this statutory authorization.¹⁴ Although the patentee does not have to justify its filing of a disclaimer under this regulatory scheme and the PTO does not screen or specifically authorize the filing of a disclaimer, the PTO nevertheless actually receives any filings authorized by Section 253 and controls placing them on the public record. Under these circumstances, the PTO has the inherent authority to reconsider whether it should have filed, or allowed the filing, of a disclaimer and to withdraw from the public record an unauthorized terminal disclaimer.¹⁵ See *Tokyo Kikai Seisakusho, Ltd.*, 529 F.3d at 1360 (“The power to

¹³ At all material times herein, Section 253 provided:

Whenever, without any deceptive intention, a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid. A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.

In like manner any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part therein, of the patent granted or to be granted.

¹⁴ A valid disclaimer must: (1) be signed by the patentee or an attorney or agent of record; (2) identify the patent and the complete claim or claims, or term being disclaimed; (3) state the extent of the patentee’s ownership interest in the patent; and (4) be accompanied by the required fee. See 37 C.F.R. § 1.321(a).

¹⁵ During the hearing held in this case, the PTO appeared to concede that it has inherent discretionary authority to withdraw a fraudulently filed disclaimer but not an unauthorized one. The significance to the PTO of the difference between the two is not clear, particularly since the filing of an unauthorized disclaimer can involve conduct akin, in substance, to constructive fraud. See *Henderson v. Henderson*, 255 Va. 122, 495 S.E. 2d 496, 499 (1998) (constructive fraud consists of “proof that a false representation of a material fact was made, innocently or negligently, and that the injured party suffered damage as a result of his reliance on the misrepresentation.”) Here, because the filing of a disclaimer requires actual authority in order to

reconsider is inherent in the power to decide.”). That conclusion is underscored by the need to ensure the integrity of the public record and considerations of justice, fairness and equity reflected in the PTO’s regulations and rules of practice, which recognize the PTO’s residual authority to act in situations not specifically addressed under its explicit statutory and regulatory authority. *See* 37 C.F.R §1.182 (the director may address those situations not specifically provided for in the regulations, according to their merit); *id.* at § 1.183 (the director is authorized to act in “an extraordinary situation” where “justice requires” the director to afford relief); Manual of Patent Examining Procedure (“MPEP”) § 1490 (“Under appropriate circumstances, the nullification of a terminal disclaimer may be addressed by filing a petition under 37 C.F.R. § 1.182 requesting withdrawal of the recorded disclaimer.”).¹⁶

The PTO argues that it is precluded from exercising its inherent authority because “that authority does not encompass powers that run contrary to the statutory authorizations granted to USPTO in the Patent Act, and neither § 253 nor § 255 indicate a power to revoke or nullify a filed terminal disclaimer on the ground of attorney mistake or negligence.” Def. Br. at 28. Neither Section 253 or 255 prohibits the PTO from withdrawing from the public record an

bind the patentee, the unauthorized filing of a disclaimer could be viewed as an implied misrepresentation pertaining to the filer’s actual authority.

¹⁶ The PTO’s position that it has no discretion in this case also appears to conflict with its position and actions in other cases and situations. For example, in other litigation in this Court, the PTO recently took the position, at least implicitly, that it does have the ability to consider and allow in its discretion the withdrawal of a disclaimer. *See President & Fellows of Harvard Coll. v. Rea*, 1:12-cv-1034, 2013 WL 2152635, at *2 (E.D. Va. May 15, 2013) (“The [PTO] noted that Harvard had never attempted to withdraw the disclaimer, so it remains part of the official, public administrative record of the Parent Patent.”). In addition, the PTO reviews and vacates *inter partes* reexaminations, despite the plain language of the statute, which makes the initial determination “final and non-appealable.” 35 U.S.C. § 312(c); *see also* MPEP § 2246 (“A petition under 37 C.F.R. § 1.181 may, however, be filed to vacate an *ultra vires* reexamination order, such as where the order for reexamination is not based on prior art patents and printed publications.”). Likewise in *Carnegie Mellon*, the PTO effectively withdrew a disclaimer that it had mistakenly filed. 105 F.2d at 867.

unauthorized disclaimer that it has placed on the public record pursuant to Section 253. Neither section therefore necessarily precludes relief in this case; and there is nothing necessarily inconsistent about the PTO's withdrawal of an unauthorized disclaimer under the circumstances of this case and the statutory and regulatory authorizations that do exist. In sum, the PTO is charged with placing on the public record certain disclaimers, it has through regulation prescribed the requirements for its placing a disclaimer on the public record, and its decision to withdraw a disclaimer that it placed on the public record would not conflict with any statutory prohibition. For these reasons, the Court concludes as a matter of law that the PTO has inherent discretionary authority to withdraw the unauthorized terminal disclaimer pertaining to the Cancer Treatment Patent.

C. The PTO's refusal to withdraw the terminal disclaimer was arbitrary, capricious and an abuse of discretion.

Although it recognized it was presented with an "extraordinary situation," the PTO justified its refusal to exercise any inherent authority it might have on two grounds. First, it reasoned that since it made no substantive decision to enter or not enter the disclaimer, "there is no decision to reconsider." FAD at 7.¹⁷ Second, the PTO ruled that in any event "the

¹⁷ The FAD stated in support of this position:

Patentee cannot point to a determination (on the merits) that the Office made that should be reconsidered. The extraordinary situation now described on [the Foundation's] petition bore no weight on the entry of the disclaimer. No substantive review of this disclaimer was undertaken [by the PTO]. No gathering of information or reviewing of evidence occurred [by the PTO]. No decision was made with respect to the merits of the entry of the disclaimer. It is noted that the question of whether the disclaimer was filed by a proper party and the question of whether assignee authorized the party to file the disclaimer are distinct questions. As the patentee's filing met the standard of being filed by a proper party and including the required fee, the office accepted the disclaimer for recording as requested.

Id. at 7.

circumstances of the filing of the disclaimer in this patent does not warrant withdrawal or nullification of the patent.” *Id.* at 8. Neither of these reasons “articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’” *State Farm*, 463 U.S. at 43.

With respect to its first grounds, the PTO essentially takes the view that since it did not create or contribute to the Foundation’s problem, it had no responsibility to fix it once it determined that the disclaimer was filed by the Foundation’s counsel of record. That position ignores that the Foundation is not bound by an unauthorized disclaimer and that the PTO is the Foundation’s only source of adequate relief. It also fails to recognize the central, gatekeeping role that the PTO does play with respect to the public record. In short, the PTO cannot responsibly cast itself as a total stranger to the Foundation’s predicament and its efforts to reverse the nullification of its patent.

Nor does the PTO’s established policy against withdrawing a recorded patent disclaimer in certain circumstances, as described in its FAD, justify its refusal to do so in this case. The disclaimer’s withdrawal in this case will not lengthen the original term of the Cancer Treatment Patent when it issued. There is no evidence that the policy has ever been applied previously to the unauthorized filing of disclaimer and there is nothing to suggest that the policy, when formulated, was ever intended to apply to the extraordinary situation in this case. Finally, for the reasons previously stated, the PTO’s other concerns and considerations pertaining to public reliance, the integrity of the filing system and administrative convenience and necessity do not constitute sufficient justification for refusing to withdraw the unauthorized disclaimer of the Foundation’s Cancer Treatment Patent. For these reasons, the Court concludes that the PTO

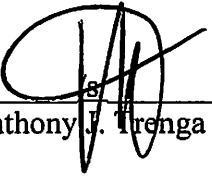
abused its discretion when it refused to withdraw the terminal disclaimer of the Cancer Treatment Patent.

c. CONCLUSION

The PTO was presented with the extraordinary circumstance of a patentee threatened with the loss of its patent because of the unauthorized filing of a disclaimer. In refusing to withdraw the unauthorized disclaimer, the PTO acted based on an erroneous legal view concerning the extent to which the Foundation was bound by its counsel's conduct and made no factual findings that would justify not withdrawing that unauthorized filing based on any particularized harm or prejudice to the PTO's institutional interests or the public interest. Nor can the Court find any such justification based on the administrative record.

For these reasons, the Court concludes that the PTO did not act in accordance with law, acted arbitrarily and capriciously, and abused its discretion when it refused to withdraw the terminal disclaimer of the Foundation's Cancer Treatment Patent for the reasons set forth in the FAD. Accordingly, the Plaintiff's Motion for Summary Judgment [Doc. No. 13] is GRANTED and the Defendant's Cross Motion for Summary Judgment [Doc. No. 22] is DENIED. The Court will therefore reverse the FAD and direct the PTO to withdraw the disclaimer of the Foundation's Cancer Treatment Patent, absent a finding that the Foundation actually authorized its filing; and this matter will be remanded to the PTO for further proceedings consistent with this Memorandum Opinion.

An appropriate Order will issue.



Anthony J. Trenga

Alexandria, Virginia
July 26, 2013